

COMMENTS AND RESPONSES

Comment on: Margolis et al. Lack of Effectiveness of Hyperbaric Oxygen Therapy for the Treatment of Diabetic Foot Ulcer and the Prevention of Amputation: A Cohort Study. Diabetes Care 2013; 36:1961–1966

The article by Margolis et al. (1) took me by surprise because multiple randomized controlled trials as well as personal experience have shown that hyperbaric oxygen therapy (HBOT) is very beneficial in the treatment of diabetic foot ulcers. After reading the article fully, I am of the belief that the authors have made a fundamental error of interpretation of their statistics, and the title is certainly not justified by their results.

Firstly, the study is retrospective data from an organization that treats patients for profit. That has implications in that reimbursement for the use of HBOT in chronic wounds is related to the duration of the wound, prior treatment, and also the severity of the wound as assessed by the Wagner grade being ≥ 3 (i.e., deep tissue infection or osteomyelitis [2]). This artificially fills the HBOT group with clinically worse ulcers.

The next concern is that initially 11,301 patients were eligible for the study, and 5,042 were excluded because they either fully healed, had amputations, or did not reduce their wound size by $>40\%$. There is no breakdown of this group at all with respect to the two study arms. The amputation rate of this group was 4.5%, and if the group followed standard funding guidelines of 30 days of conventional treatment prior to HBOT, then this should be added to the data for the non-HBOT group.

Randomized controlled trials from multiple authors, including two recent well-designed ones by Löndahl et al. (3), Duzgun et al. (4), and others have shown significantly higher rates of healing in HBOT groups versus standard care groups.

The implication that is made in the conclusion that HBOT is used in wound care in isolation is also incorrect because it is always used in conjunction with best wound care practices (which may include skin substitutes and certainly offloading of the foot). HBOT is usually not introduced until conventional treatment has been shown to be ineffective after 3 months, so the average wound time of 1 month prior to presentation and then 28 days of “conventional treatment” is short by most facility standards around the world.

The groups could also not be compared because the HBOT group had significantly bigger wounds, had a higher distribution of males, and had a significantly longer duration of wound. All of these factors with the higher Wagner grading would suggest that the HBOT group had more likelihood of having an amputation regardless of the treatment modality used. This therefore is not a cohort comparison of HBOT versus standard wound care but a cohort of smaller less serious wounds versus larger, longer

duration, deeper wounds; not surprisingly, there were more amputations and slower healing rates in the second group. The question is therefore, is the HBOT group rate of amputation significantly reduced versus what would be expected in this wound cohort?

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